DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB 15 2011

Re: AMPYRA
Patent Nos.: 5,370,879 and 5,540,938
Docket Nos.: FDA-2010-E-0484
FDA-2010-E-0483

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 5,370,879 and 5,540,938, filed by Elan Pharma International Ltd., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for AMPYRA (dalfampridine), the human drug product claimed by the patents.

The total length of the regulatory review period for AMPYRA (dalfampridine) is 9,845 days. Of this time, 9,569 days occurred during the testing phase and 276 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: February 10, 1983.

   The applicant claims January 1, 1980, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND was initially placed on clinical hold. The applicant was informed that the investigational studies were allowed to proceed on February 10, 1983, the effective date of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: April 22, 2009.

   FDA has verified the applicant's claim that the new drug application (NDA) for AMPYRA (NDA 22-250) was submitted on April 22, 2009.

3. The date the application was approved: January 22, 2010.

   FDA has verified the applicant's claim that NDA 22-250 was approved on January 22, 2010.

This determination of the regulatory review period by FDA does not take into account the effective date of the patents, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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